11.0 510(K) SUMMARY

DESCRIPTION

The Synthes VentroFix MIS System consists of a range of plate sizes and 7.0 mm bone screws. The plates attach to the anterolateral aspect of the vertebral body of the thoracolumbar spine (levels T1-L5) and provide stabilization to permit the biological process of spinal fusion to occur. All components are manufactured from Titanium alloy.

INDICATIONS

The Synthes VentroFix MIS System is indicated for use, via the lateral or anterolateral surgical approach, in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of degenerative disc disease (defined as pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spondylolysis, fracture (including dislocation and subluxation), spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis whether neuromuscular or related to deficient posterior elements), tumors (neoplastic disease), pseudoarthrosis, or a failed previous fusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2004

Susan Lewandowski
Project Manager, Regulatory Affairs
Synthes (USA)
1380 Enterprise Drive
West Chester, Pensylvania 19380

Re: K031100
Trade/Device Name: Synthes VentroFix MIS System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 29, 2003
Received: December 30, 2003

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INDICATIONS FOR USE FORM

510(k) Number (if known): K 031100

Device Name: Synthes VentroFix MIS System

INDICATIONS FOR USE:

The Synthes VentroFix MIS System is indicated for use, via the lateral or anterolateral surgical approach, in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of degenerative disc disease (defined as pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spondylolysis, fracture (including dislocation and subluxation), spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis whether neuromuscular or related to deficient posterior elements), tumors (neoplastic disease), pseudoarthrosis, or a failed previous fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ OR Over-The-Counter Use___ ___
(Per 21 CFR § 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K 031100